

## Publications

### *Client Alert: 2018 “Farm Bill” Creates New Opportunities for Patients, Producers of Hemp-Derived CBD*

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On December 20, 2018, President Trump signed the Agricultural Improvement Act of 2018, popularly known as the “Farm Bill” of 2018, into law.

Among other things, the Farm Bill amends the federal Controlled Substances Act (CSA) to exclude “hemp” – defined as any part or derivative of the plant *Cannabis sativa* with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3% on a dry weight basis – from the legal definition of marijuana. The Farm Bill also authorizes new state and federal programs to regulate the production and distribution of hemp.

This new legislation is of particular significance to proponents of medical cannabis, who have long advocated for legal recognition of the distinction between cannabidiol (CBD) derived from marijuana and CBD derived from hemp. By way of background, marijuana and hemp are two species of the *Cannabis sativa* plant, cultivated for distinct purposes. Today, hemp plants and products contain minimal THC (the psychoactive component of the cannabis plant more prevalent in marijuana), and are instead used primarily for industrial purposes. Hemp plants do, however, contain CBD, one form of which (GW Pharmaceuticals’ Epidiolex) recently became the first cannabis-derived drug to receive approval from the federal Food and Drug Administration (FDA).<sup>[1]</sup>

Through the Farm Bill, Congress has created a legal mechanism to allow for the regulation of hemp products, including appropriately-sourced CBD, separate from that of marijuana. Specifically, the Farm Bill requires the Secretary of Agriculture to establish a procedure for the licensing of hemp producers, which must include:

- A practice to maintain information regarding land on which hemp is produced;
- A procedure for testing products’ THC concentration levels;

- A procedure for the effective disposal of plants and products that do not comply with legal limitations;
- A procedure for enforcement; and
- Any other practices or procedures the Secretary considers to be appropriate.

The Farm Bill also authorizes States and Indian tribes to establish their own regulatory plans for hemp, subject to approval by the U.S. Department of Agriculture (USDA). A producer in a State that elects not to establish such a plan may nonetheless apply for and receive a federal license, so long as his or her State has not prohibited the production of hemp. Notably, no State may prohibit the shipment of federally-compliant hemp products through its territory.

Once these regulatory programs take effect, products derived from hemp (including CBD) will be fully legal to produce, possess, and/or sell under federal law. Importantly, however, Ohio law does not currently distinguish between marijuana and hemp, and includes no exception for a cannabis derivative based on its THC content.<sup>[2]</sup>

Additionally, sellers and producers of CBD should be aware that the FDA takes the position that CBD does not qualify as either a drug or a dietary supplement. Accordingly, the federal Food, Drug, and Cosmetic Act (FDCA) prohibits the use of either (1) “disease claims” (statements that claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases) or (2) “structure/function claims” (statements that claim physical benefits or effects from the consumption of a nutrient or dietary ingredient) in the advertising of CBD.

If you have questions regarding the new law, medical cannabis generally, and/or the regulation of drug and dietary supplement advertising, please contact Jolie Havens, Elizabeth Smith, Matt Albers, Mairi Mull, or your regular Vorys attorney.

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[1] See our alert regarding the FDA’s clearance of Epidiolex [here](#).

[2] The Ohio Board of Pharmacy has previously taken the position that there is no basis in Ohio law to distinguish between CBD oil sourced from marijuana and that sourced from hemp, meaning that hemp-derived CBD is subject to the requirements of the Medical Marijuana Control Program (read the Board’s full statement [here](#)). The Vorys team is seeking additional information regarding the Board’s response to the amendment of the federal CSA.